EXHIBIT A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Jens PETERSEN
Title:	**POLYACRYLAMIDE HYDROGEL AND ITS USE AS AN ENDOPROSTHESIS**
Appl. No.:	09/938,670
Filing Date:	08/27/2001
Examiner:	Cheryl Miller
Art Unit:	3738

DECLARATION UNDER 37 CFR § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

(1) I, Robert Lessél, am an expert in polymer chemistry ("the field"). My qualifications as an expert in the field are detailed in a curriculum vitae that is an APPENDIX 2 to this Declaration.

(2) I provide consultation and know-how to Contura S.A. pursuant to an agreement on matters of process polymer chemistry.

(3) I have reviewed the pending claims of the subject application. Additionally, applicant's representative to the PTO has informed me of certain issues that have arisen in the prosecution of the subject application. Furthermore, the applicant's representative to the PTO has informed me of certain amendments to the claims of the subject application in relation to specifying the relative insolubility of the polymer hydrogel of the invention in water and in specifying the biological stability of the hydrogel of the invention. The applicant's representative to the PTO has informed me of certain amendments to the claims have furthermore been made in lowering the upper limit of the viscosity range. The applicant's representative has informed me that my opinion is required on issues of solubility, biostability and viscosity in the context of cited art.

(4) Accordingly, with respect as to whether the hydrogel of Purkait is water soluble, the person skilled in the art immediately understands from Purkait teaches that all or almost all of the composite hydrogel is non-crosslinked polyacrylamide. The person skilled in the art knows that non-cross linked polyacrylamide is water soluble. Purkait accordingly describes a composite hydrogel material wherein the major component is very water soluble, as understood by the person skilled in the art. In Purkait, a minor component may or may not be water insoluble. In contradistinction, the present invention relates to a product, as understood by the person skilled in the art merely by the components of the polymerization process, which is not, in whole or in part, water soluble.

(5) It is my understanding that the applicant has furthermore specified the insolubility of the polymer in the claim itself. Irrespective of whether the insolubility is specified in the claim, based upon a teaching in the claim to polymerize acrylamide in the presence of methylene-bis-acrylamide, the person skilled in the art, would generally understand the resultant product to be as a whole water insoluble, particularly at the defined molar ratios of the components. Purkait teaches of a composite hydrogel which is substantially water soluble with a possible minor component in the composite hydrogel which may or may not be water insoluble.

(6) Accordingly, the person skilled in the art understands Purkait to describe a polymer composite which is substantially water soluble in contradistinction to the present invention which teaches, (and apparently now specifies) a polymer that is not water soluble.

(7) As to whether the Purkait composite hydrogel is biostable, it is readily understood by the person skilled in the art that Purkait composite hydrogel serves as a filling material for an endoprosthesis rather than as an endoprosthesis itself. This is a fundamental difference between the materials: Purkait describes a filling material which is intended to be biologically unstable in the undesired even of having contact with human tissue whereas the present invention describes a material which is stable when in contact with human tissue. This stability allows it to function as an endoprosthesis; moreover, a permanent endoprosthesis.

(8) Purkait repeatedly states that the material is to be encapsulated in an envelope and that leakage is an unwanted scenario. In the event of leakage from the silicone envelope, the composite material is to be eliminated. In order to be eliminated, the material must be degraded. Accordingly, the person skilled in the art understands Purkait to describe a polymer

composite which is substantially biologically degraded. From our reading of Purkait, a 2% component of the substantially biologically unstable composite hydrogel of Purkait may be biologically stable. When reading Purkait, the person skilled in the art understands that the residual 2% material is undesirable. The person skilled in the art learns from Purkait that biological stability is not desirable. In contradistinction, the claims of the present invention describe a polymer which, in its entirety, would be permanent and biologically stable when in contact with the human body.

(9) With regards to Annis, I have read the Office Action, the Examiner's objections, and the Interview Summary. I understand that the Examiner requires clarification regarding the complex viscosity of the present invention in relation to that of Annis.

(10) Annis does not explicitly define the viscosity of the polymer hydrogel. However, the person skilled in the art, based upon a reading of Annis as a whole, would immediately recognize that the Annis material would generally be outside the claimed values for complex viscosity. Annis describes a polymer hydrogel that is substantially rigid compared to the present invention which describes a non-Newtonian fluid-like material.

(11) Annis describes a material which is "sized and formed" (column 2, line 16), typically into a "kidney shaped" (column 3, lines 38-39) with defined (and more importantly, definable) dimensions. It is immediately evident to the skilled person that the Annis material has a much higher viscosity (and likely elasticity) than the values defined for the hydrogel of the present invention.

(12) Annis describes (column 2, lines 23-26) that the material should have the same physical properties as "natural tissues". As a person skilled in the art, based upon my understanding and my experience in working with polymeric materials intended for use inside a human or animal body, this inherently describes the Annis material as having a viscosity typically in the range of 95-900 Pas. It must be noted however that some forms of animal tissue may have a viscosity as low as 90 Pas, perhaps even 85 Pas.

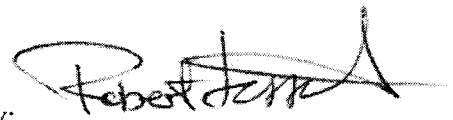
(13) A homogenized polymer hydrogel having a complex viscosity of 2 to 60 Pas is fluid-like. It possesses non-Newtonian fluid characteristic (hence the descriptor "complex viscosity" rather than "viscosity"). Temporarily disregarding the not entirely academic distinction between "complex viscosity" and "viscosity", I will comment upon the complex viscosity

feature of the claimed invention. Homogenized non-Newtonian fluids having a complex viscosity of 2 to 60 Pas cannot support their own weight over an extended period of time. Without the constraints of a container or frame, such as material collapses under its own weight into a formless mass. Such materials cannot be defined in terms of its shape. This is in contradistinction to the material defined by Annis which is formed and shaped and maintains its shape.

(14) A more detailed reading of Annis further allows the skilled person that the material by Annis would have physical properties that could allow sutures to secure the material. In contradistinction, the polymer hydrogel of the present invention, with the defined complex viscosity, would immediately be understood by the person skilled in the art not to be suitable for sutures since it would not be resistant enough to hold a suture. To illustrate the inappropriateness in layman terms, it would be like trying to sew Vaseline or mayonnaise to Jell-O that wasn't ready yet. In short, the complex viscosity values of the polymer hydrogel of the present invention are well below what would be inherently understood by the teaching of Annis.

(15) I further declare that all the statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements are so made punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 30 oct 2008

By: 

Robert Lessèl, Chempilots a/s
Farum, Denmark

CURRICULUM VITAE

Name:	Robert Lessèl.
Nationality:	Danish.
Address:	Bryggerdammen 21, 2605 Brøndby, Denmark.
Telephone:	3675-8830.
Born:	6. august 1963 in Glostrup, Copenhagen.
Personal status:	Married, 3 children age 8, 14 and 17.
Education:	1982: Graduated high school, Statsgymnasiet Schneekloths skole 1988: M. Sc.(Eng.), Chemical Engineer, Technical University of Denmark, specialized in polymer chemistry. Examination work: Modification of polymeric membranes and Phenyl substituted aromatic liquid crystalline polymers. 1989: Patent Examiner at The Danish Patent Office. 1996: Examined as Project Manager, ETM, IHB-Denmark. 2003: Introduction to Management, Right Kjaer & Kjerulf.
Employments:	October 1988 - December 1990 Patent Examiner at The Danish Patent Office within the area "Phosphoric Compounds and polymers". January 1991- ...: Project Manager and Consulting Engineer within polymeric chemistry & processing at Chempilots a/s (previously Wolff & Kaaber A/S). Chempilots work has included: Independent problem-solving, preparation of experimental plans, experiments in the laboratory and at the client, reporting and follow up. Internal/external collaboration with scientific and technical staff including direct

customer contacts with several Danish and International companies, mainly from the Medical Device industry.

Examples of major Projects:

1991: "Development of effective resin composites as substitute for amalgam", performed in association with Dr. Odont E.C.Munksgaard, Dental School, Copenhagen.
The project is supported by the Danish Environmental Protection Agency.

1994-2000: MUP II program: "Stability and strength of the bonds between polymers and the inorganic fillers", in association with the Danish company Nordisk Tråd & Kabel A/S (NKT research center) and two state laboratories at H C Ørsteds institute, University of Copenhagen and Risø, Department of Solid state Physics.

1999-2002: Thor program: " Design of new functional polymer composite Materials"; exploration of the use of supercritical CO_2 as solvent in preparation and modification of polymeric based materials.

Optimization of Bone Cement formulation, Polyurethane foam and Controlled Release system. Processing assignments with regards to Casting of plastic Fresnel screens. Synthesis of Polymer based materials used as conducting/medical skin adhesives and ECG, and development and synthesis/ analysis of polymeric based Hydrogel products for use as colorants for soft contact lenses and soft tissue filler.

Handling of patent applications internally and for customers including elaboration of patent applications, forming strategies and drawing up budgets, correspondence with Danish and foreign patent agents.

Supplementary achievements and references:

Participated regularly in national and international congresses, courses, meetings and workshops since 1988 within the scientific areas of Polymer Chemistry and Technology, Synthesis and processing of Polymer based Hydrogels, Characterization and Analysis of Polymeric based materials and Patent related topics.

Training courses in HPLC, Perkin Elmer.

Trained in ISO9001 and GMP for use in laboratory and production.

Trained in literature searching using STN incl. Chemical Abstract.

Taken classes in Taguchi experimental planning and Statistic with Statgraphic, DIEU.

Teaching experience & publications :

1990: Instructor in Patent examination, The Danish Patent Office.

1991: Internal lecture, Topic: Patents - protection of research and development.

1992: Lecture for leading staff at dnp denmark A/S, topic: Polymerization processes in manufacturing of Fresnel screens.

1995: Invited speaker to a meeting arranged by the DSM, a society under The Society of Danish Engineers, topic: Use of polymeric composite materials instead of amalgam.

2004: Invited speaker at the annually meeting in the Society of Processing in Organic Chemistry, Cheminova: Use of Supercritical CO_2 in Organic Chemistry.

2000: Co-inventor on several patent applications regarding polyacrylamide based hydrogels.

1990: M.H.B. Skovby, R. Lessèl and J. Kops, J.: Thermal

properties of Some Fully Aromatic Thermotropic Liquid Crystal Polyesters Polym. Sci. A. Polym. Chem. Ed., 28, 75 (1990)

1990: Article i Patentdirektoratets personaleblad om "Nordiske Polymerdagar 1990", R. Lessèl, 9/1990.

1992-1998: Munksgaard, EC, Wolff & Kaaber A/S: Erstatningsmaterialer for sølvamalgam, Arbejdsrapport, Miljøstyrelsen 1992, 1994, 1997 og 1998

1996: Artikel i Tandlægebladet: Plastfyldninger i støbeskeen, 100, 1996, s. 190 -191

1997: Interview til Materiale & Muligheder: Ny viden om avanceret plast.

1998: Munksgaard, EC, Wolff & Kaaber A/S: Erstatningsmaterialer for Amalgam til tandfyldninger, Projektrapport, Miljøstyrelsen 1998

1997: Lessèl, R; Elbek, C: Rheological Characterization of highly filled dental restorative composite in the uncured state; Poster at Nordic Polymer Days, Lund.

2000: Egsgaard, H; Batsberg, W; Møllgaard, M; Lessèl, R; Glastrup, J: Mass spectrometry of Polyethylene Glycols; Proceeding and poster at International MS meeting in Barcelona.

Schaumburg, K; Jespersen, H.T; Khokhlov, A; Karthäuser, J; Lessèl, R: Kemi i superkritisk CO_2; dansk kemi, 84, nr. 11, s. 26 – 30.

Memberships:

1990: Member of the Advisory committee on the project "Development of effective resin composites as substitute for amalgam", appointed by the Danish Environmental Protection Agency.

1999-2002: Member of the Steering group FUCOMA in the public financed THOR project " Design of new functional polymer composite materials".

2008- : Member of the board of the Danish Society for Polymer Technology under the Danish Society of Engineers, IDA.

EXHIBIT B

Errata: A Practical Approach to Rheology and Rheometry

The author apologizes for the following errors, which had not been eliminated before printing. The reader is asked to correct his book copy manually:

Page 46:

$$\dot{\gamma}_r = \frac{R_i^2}{r^2} \cdot \left(\frac{1+\delta^2}{\delta^2-1}\right) \cdot \Omega \cdot$$

must be:

$$\dot{\gamma}_r = \frac{R_i^2}{r^2} \cdot \left(\frac{2\cdot\delta^2}{\delta^2-1}\right) \cdot \Omega \cdot$$

Page 52:

$$\delta_1 = 1.01 \rightarrow \dot{\gamma}_1 = \frac{\pi}{15} \cdot \frac{1.02}{0.2} \cdot n \approx 10.2 \cdot n$$

$$\delta_2 = 1.10 \rightarrow \dot{\gamma}_2 = \frac{\pi}{15} \cdot \frac{1.21}{0.21} \cdot n \approx 1.16 \cdot n$$

$$\delta_3 = \infty \rightarrow \dot{\gamma}_3 = \frac{\pi}{15} \cdot \frac{\infty}{\infty} \cdot n \approx 0.105 \cdot n$$

Example: Fig. 30 indicating the influence of gap sizes on viscosity data when non-Newtonian liquids are tested.

for n = 10 rpm

$\dot{\gamma}_1 = 102$ 1/s $\Rightarrow \eta_1 = 6.78$ mPas
$\dot{\gamma}_2 = 11.6$ 1/s $\Rightarrow \eta_2 = 10.72$ mPas
$\dot{\gamma}_3 = 2$ 1/s $\Rightarrow \eta_3 = 16$ mPas

must be:

$$\delta_1 = 1.01 \rightarrow \dot{\gamma}_1 = \frac{\pi}{30} \cdot \frac{2.0201}{0.0201} \cdot n \approx 10.60 \cdot n$$

$$\delta_2 = 1.10 \rightarrow \dot{\gamma}_2 = \frac{\pi}{30} \cdot \frac{2.21}{0.21} \cdot n \approx 1.10 \cdot n$$

$$\delta_3 = \infty \rightarrow \dot{\gamma}_3 = \frac{\pi}{30} \cdot \frac{\infty}{\infty} \cdot n \approx 0.105 \cdot n$$

Example: Fig. 30 indicating the influence of gap sizes on viscosity data when non-Newtonian liquids are tested.

for n = 10 rpm

$\dot{\gamma}_1 = 106.0$ 1/s $\Rightarrow \eta_1 = 6.78$ mPas
$\dot{\gamma}_2 = 11.60$ 1/s $\Rightarrow \eta_2 = 10.72$ mPas
$\dot{\gamma}_3 = 1.05$ 1/s $\Rightarrow \eta_3 = 19$ mPas

Page 79: second line in second paragraph:
...beads introduce the intermolecular elastic behaviour...
must be: ...beads introduce the intramolecular elastic behaviour...

Page 89: equation at page end
$\psi_1 = \eta / \dot{\gamma}$ [Pa · s²]
must be: $\psi_1 = N_1 / \dot{\gamma}^2$ [Pa · s²]

Page 91: last line of first paragraph:
...as Fig. 54 not just one but three decades of shear rate...
must be: ...as in Fig. 54 not just three but six decades of shear rate...

Page 124: second line in third paragraph:
...the relaxation time $\lambda = 1 / (G'' \cdot \omega)$...
must be: ...the relaxation time $\lambda = G' / (G'' \cdot \omega)$...

HAAKE
Rheometers

A Practical Approach to Rheology and Rheometry

by
Gebhard Schramm

Gebrueder HAAKE GmbH, Karlsruhe,
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HAAKE
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2.3 Shear rate

The shear stress τ causes the liquid to flow in a special pattern. A maximum flow speed v_{max} is found at the upper boundary.

The speed drops across the gap size y down to $v_{min} = 0$ at the lower boundary contacting the stationary plate. Laminar flow means that infinitesimally thin liquid layers slide on top of each other, similar to the cards in a deck of cards. One laminar layer is then displaced with respect to the adjacent ones by a fraction of the total displacement encountered in the liquid between both plates. The speed drop across the gap size is named "shear rate" and in it's general form it is mathematically defined by a differential.

☞Please note

Inasmuch as normal typewriters and computers are not able to print "$\dot{\gamma}$" it is also common to use the letter "D" to indicate shear rate.

$$\dot{\gamma} = \frac{dv}{dy} \qquad [4]$$

$$\dot{\gamma} = \frac{m/s}{m} = \frac{1}{s} = [s^{-1}]$$

In case of the two parallel plates with a linear speed drop across the gap the differential in the equation reduces to:

$$\dot{\gamma} = \frac{v_{max}}{y} \; [s^{-1}] \qquad [5]$$

☞Please note

In the scientific literature shear rate is denoted as $\dot{\gamma}$. The dot above the γ indicates that shear rate is the time-derivative of the strain caused by the shear stress acting on the liquid lamina.

$$\dot{\gamma} = \frac{dy}{dt} = \frac{\frac{dL}{dy}}{dt} = \frac{\frac{dL}{dt}}{dy} = \frac{dv}{dy} \qquad [6]$$

Mathematical treatment can show that equations [4] and [6] are equal.
Equation [2] can be rewritten making use of equation [6]:

$$\tau = \eta \cdot \frac{dv}{dy} = \eta \cdot \dot{\gamma} \qquad [7]$$

Comparing equations [1] and [7] indicates another basic difference between solids and liquids: Shear stress causes strain in solids but in liquids it causes the rate of strain. This simply means that solids are deformed while liquids flow. The parameters G and η serve the same purpose of introducing a resistance factor linked mainly to the nature of the body sheared.

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2.4 Dynamic viscosity

Solving equation [2] for the dynamic viscosity η gives:

$$\eta = \frac{\tau}{\dot{\gamma}} \qquad [8]$$

$$\eta = \frac{N}{m^2} \cdot s = [Pa \cdot s]$$

The unit of dynamic viscosity η is the "Pascal · second" [Pa·s]. The unit "milli-Pascal · second" [mPa·s] is also often used.

$$1 \text{ Pa} \cdot \text{s} = 1000 \text{ mPa} \cdot \text{s}$$

It is worthwhile noting that the previously used units of "centiPoise" [cP] for the dynamic viscosity η are interchangeable with [mPa·s].

$$1 \text{ mPa·s} = 1 \text{ cP}$$

Typical viscosity values at 20°C [mPa·s] :

Petrol	0.65	Coffee cream	≈ 10
Water	1.0	Honey	$\approx 10^4$
Mercury	1,5	Polymer melts	$\approx 10^3 - 10^6$
Grape juice	2 - 5	Bitumen	$\approx 10^8$
Blood [at 37°C]	4 - 15	Glass	$\approx 10^{23}$

2.5 Kinematic viscosity

When Newtonian liquids are tested by means of capillary viscometers such as Ubbelohde or Cannon Fenske, viscosity is determined in units of kinematic viscosity υ. The force of gravity acts as the force driving the liquid sample through the capillary. The density of the sample is one other additional parameter.
Kinematic viscosity υ and dynamic viscosity η are linked:

$$\nu = \frac{\eta}{\rho} \quad [mm^2/s] \qquad [9]$$

υ = Kinematic viscosity
Former units of kinematic viscosity were:
"Stokes" [St] or "centi Stokes" [cSt].

1 St = 100 cSt $\qquad 1 \; [\frac{mm^2}{s}] = 1 \; [cSt]$

ρ = density $\qquad [kg/m^3 = \frac{N \cdot s^2}{m^4}]$

☞Please note:

"Ford-cup seconds", "Engler degrees" and "Saybolt or Redwood seconds" are only viscosity related values, which (for non-Newtonian liquids) cannot be converted to the absolute viscosity values of either η or υ .

EXHIBIT C

Sheepscot

DISPENSING SYSTEMS

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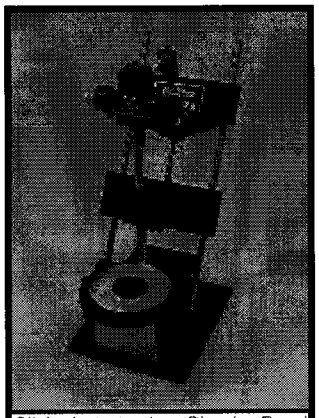

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Sheepscot Dispensing Systems builds high quality equipment for the dispensing of single-component fluids and plural-component reactive resins such as epoxies, urethanes, and silicones. For over twenty-five years, we have designed and manufactured both standard and custom dispensing products for customers in the Americas, Europe and Asia. First developed in 1978, Sheepscot's positive displacement piston metering systems have gained a reputation for rugged dependability and accuracy.

Sheepscot utilizes positively actuated ball valves on its meter, mix and dispense systems to divert material into and out of the metering cylinders. This ensures a high consistency of flow and accuracy of the ratioed material on the output stroke of the cylinders.

Additionally, Sheepscot's incrematic design optimizes long term performance by utilizing the full stroke of the large metering cylinders to make a series of shots, thus reducing the amount of linear travel (and wear) associated with a given volume of material.

For those applications that require precise flow rate control, or those which demand higher flow rates than are practical with our piston metering products, we offer our line of Stainless, Servo Driven Gear Pump systems. Long noted for their precision, reliability and simplicity, their unique design offers virtually pulseless flow.

Our Meter, Mix and Dispense Systems and other adhesive dispensers are

offered for a variety of processes:

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- Vacuum Encapsulation of electrical and electronic components
- Filtration manufacturing and end cap bonding
- Doming of printed labels
- XYZ Motion. Sheepscot designs and builds motion systems to suit your application and can integrate them either with our plural component Meter, Mix and Dispense Systems, or our single component adhesive dispensers
- Simple adhesive dispensers such as the SM-985 Dispensing Controller or S-900 Series Dispense Valves

We invite you to browse our site and review our line of meter, mix and dispense equipment, as well as our other adhesive dispensing products. We also invite you to call us with your questions about how Sheepscot can improve your production.

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